

***The Love/Avon Army of Women:
A New Model for Democratizing Research***
a program of the
Dr. Susan Love Research Foundation

Dr Susan Love, MD, MBA
September 14, 2010

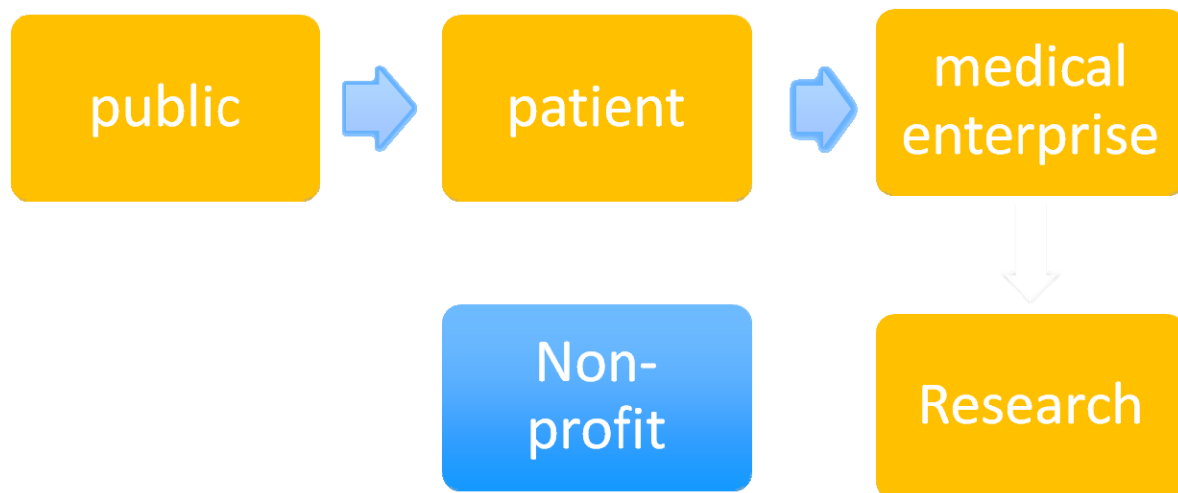
Our Mission

The Dr. Susan Love Research Foundation (DSLRF) is working to eradicate breast cancer and improve the quality of women's health through innovative research, education and advocacy.

Our goal is to identify the barriers to research, to explore new approaches and create new solutions.

We are working to move breast cancer BEYOND A CURE through innovation and collaboration.

Problem



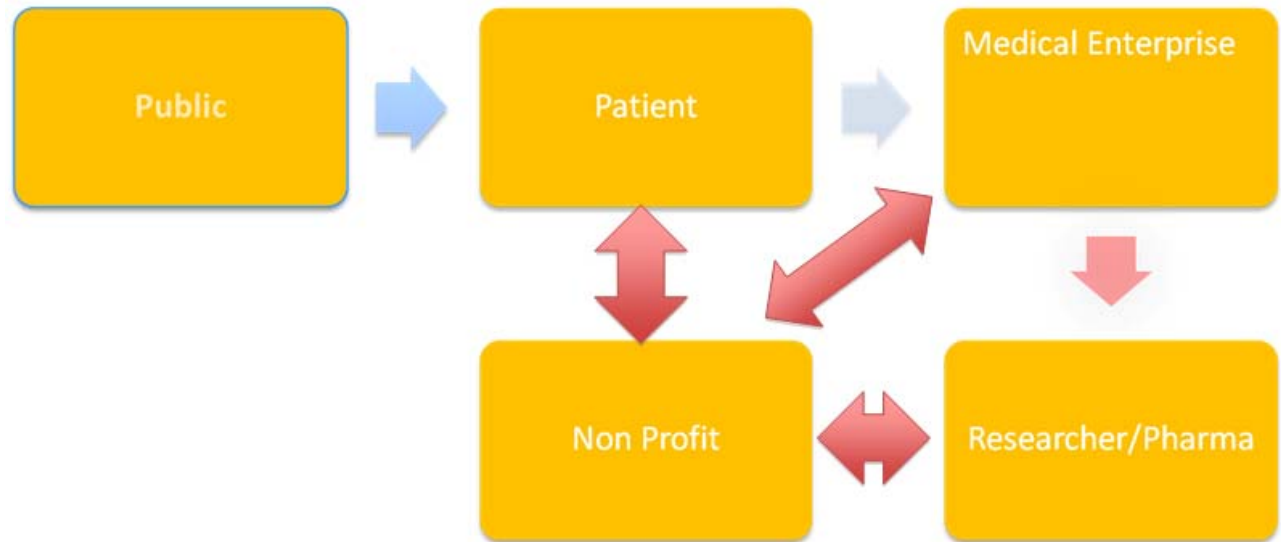
Love/Avon Army of Women

- Goal:
 - To accelerate research that will address clinical problems: Moving from Animal Models to Women
- Background:
 - Old model: investigator initiated research.
 - Alternative model: public and non-profit initiated/facilitated research.
- Problem:
 - How to accelerate/initiate/facilitate research on clinical problems
 - Accessible bio-specimens
 - Accessible data
 - Accessible clinical trial participants
 - Chronic diseases
 - Acute diseases

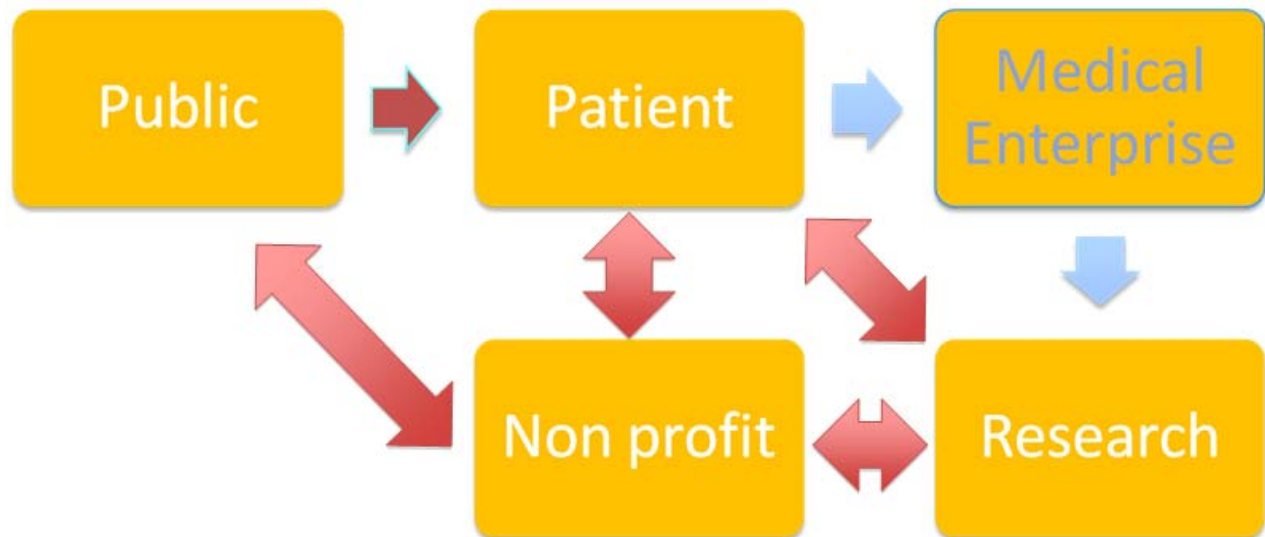
Current Models

- Registry of people with a disease:
 - Collect information in a database
 - Researchers come up with questions and solicit participants/data from those that match their criteria
 - eg. Breast Cancer Trials.org
- Listings of studies:
 - Research designed studies are listed and potential participants can search for a match
 - www.Cancer.gov
- Open database of people interested in participating in research
 - Love/Avon Army of Women

Disease Registry Bio-specimen Model



Direct with the Public Model



Solutions

Registry

- Specific recruitment
 - Currently recognized risk factors
 - People with disease
- Database for matching
 - Needs to be kept current
 - Limited to what is known
- Biobank
 - Technology of today
- Limitations
 - Expensive
 - Lot of work
 - May preclude discovering new information
- Benefits
 - ownership

Open Database

- Open recruitment
 - Willing to consider participating in research
 - Healthy, predisease, disease
- Broadcast email list
 - Participants self select
 - Adaptable to new hypothesis
- Just in time tissue and fluid collection
 - No storage
 - Adaptable to new technologies
- Limitations
 - No ownership
- Benefits
 - Less expensive
 - Can accommodate rare and common diseases

Love/Avon Army of Women

- Funded by a grant from the Avon Foundation.
- Encourage women to take the next step in breast cancer advocacy and participate in research.
- Get women invested in the concept of research to find the answers.
- Forge a partnership between women and researchers to end breast cancer.
- Increase the amount of research focused on the cause and prevention of breast cancer.
- Accelerate research by accessing a pool of ready volunteers.
- Encourage researchers to study clinically important questions.

Love/Avon Army of Women: How it Works

- Members
 - Women sign up online (www.armyofwomen.org) to receive email announcements of available studies.
 - If they are fit and are interested they RSVP and go through online screening.
 - They are passed on to the researchers.
- Researchers
 - Submit their studies online for approval by the Scientific Advisory Committee.
 - Obtain IRB approval for online recruiting.

Love Avon Army of Women

- Over 337,000 women recruited, 80% healthy, 20% survivors
- 35 studies launched, 17 studies closed, 6 studies increased recruitment due to success
- Many studies reach full recruitment within week
- An active and growing Scientific Advisory Committee of 20 members
- A successful Foot Soldier Program with over 1200 members
- Regular PR and blog mentions, including Time Magazine, Glamour, Today Show and much more.

Partnership between women and researchers

- Researchers are responsible for explaining the research to the participants as well as communicating the aggregate results of the study at the end
 - In person if they are conducting the study themselves
 - Through an AOW webinar if we are collecting samples and shipping to them

Army of Women

- 35 “call-to-action” e-mails sent to the Army of Women
- 17 closed to enrollment after successful accrual
- 1 global study, 16 national studies, 18 regional studies
- Over 44,000 members registered to enroll in studies
- Types of Studies
 - QOL / psycho-social
 - Diet / exercise (effect on biomarkers, hormones, insomnia, and fatigue)
 - Biomarkers (milk, breast tissue, breath condensate)
 - Survivor education/information delivery
 - Etiology: Colonic Microbiota/ breast hormones
 - DCIS and BRCA ½
 - Hot flashes
 - Chemoprevention

Army of Women

Local Research Studies

- The Beam Study (Breast Estrogen and Methylation) at Northwestern University and Johns Hopkins (launched 7/22/09): A study of using DNA methylation and breast tissue hormone concentrations to provide an individualized breast cancer risk profile.
 - 300 women required
 - 10,617 total responses from the AOW
 - 300 RSVP

AOW recruitment highly successful

- NU 51 in 16 months (23 after AOW eblast)
- JHU 34 in 5 months (all AOW)

Researcher comments: Volunteers are well-informed, highly motivated, compliant, and the ratio of eligible to ineligible very high.

National Research Study

- NIH/NIEH Funded Sister Study (launched 10/23/08, closed 3/30/09): A national study that began in 2002 to study how environment and genes affect breast cancer risk.
 - 5,000 women needed
 - 52,411 total responses from the AOW
 - In 48 hours: 1600 recruited
 - In two weeks 2300 recruited
 - 5000 recruited

Army of Women

National Research Studies

- Avon Funded Milk Study (launched 11/17/2008) Biomarker study at UMass recruiting lactating women scheduled for a breast biopsy.
 - 250 women required
 - 62,826 total responses from the AOW
 - In 24 hours: 31 recruited (representing a 6 month acceleration of recruitment)
 - To Date: 324 recruited
 - Study enlarged to 1000

Local Research Study

- NIH and DSLRF funded Obesity Study (launched 1/7/2009, closed 1/9/09): A controlled diet and exercise study at UCLA monitoring markers of risk for breast cancer.
 - Needed 20 subjects
 - 21,868 total responses from the AOW
 - In 12 hours, fully enrolled
 - 125 recruited

Army of Women

Local Research Studies

- NIH funded Cognitive and Emotional Effects of Breast Cancer study at Stanford University (launched 4/16/2009, closed 5/4/09): A study using imaging, genetic markers, and neuropsychological testing to define the cognitive deficits associated with breast cancer and chemotherapy.
 - 180 women required
 - 16,446 total responses from the AOW
 - 1314 recruited

Army of Women

Local Research Studies

- A CBCRP funded Grapefruit Study at the University of Southern California, (launched 5/5/09, closed 5/7/09): Assessing the effect that the regular intake of grapefruit has on hormones in postmenopausal women.
 - 65 women needed
 - 12,126 total responses from the AOW
 - 203 recruited

Army of Women

National Research Studies

- An NIH-funded study, Variations in Health Needs of Breast Cancer Survivors at Boston University (launched 6/10/09): QOL study to reduce the disparity in cancer burden due to sexual orientation.
 - 100 lesbian, bisexual women required
 - 15,412 total responses from the AOW
 - 158 recruited

Army of Women

National Research Studies

- An NIH-funded study, The Patient-Physician Interface: How Breast Cancer Patients Navigate Fertility Concerns and Treatment Options at Northwestern University (launched 8/5/09): A study of how younger women and their doctors discuss the issue of possible fertility impairment due to cancer treatment.
 - 15 AA women diagnosed prior to age 40
 - 10,833 total responses from the AOW
 - 20 recruited

Next Steps

A model for 21st century

Empower women (the public) to be part of and feel invested in research

- By educating women in the research process
- By including women in the collection and maintenance of data
- Through engaging women in figuring out the key clinical questions of the day
- Through the first large totally internet based cohort:

Health of Women Study

- Partnership between:
 - City of Hope: Leslie Bernstein Ph.D and Katherine Henderson Ph.D
 - NCI's CaBIG
 - Dr. Susan Love Research Foundation
- Online cohort study
 - Periodic modules/questioners
 - Engage the public
- Beta launch to existing Army of Women members
 - 20% (25,414) have completed first module/questioner
 - 80% do not have breast cancer

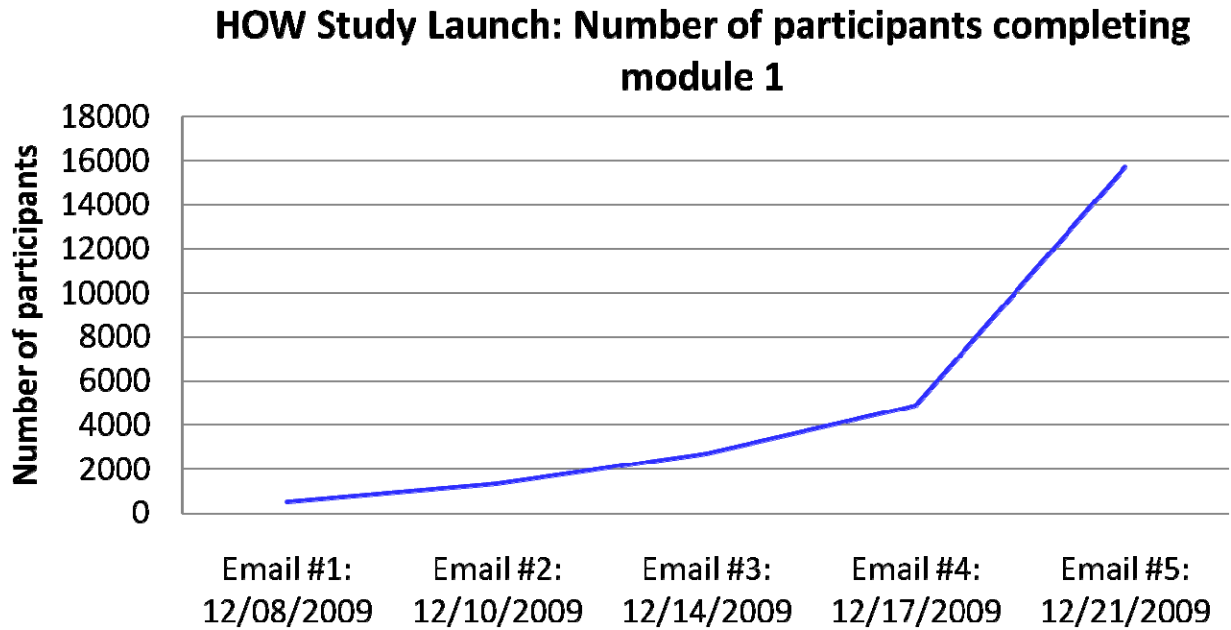
Purpose

- Accelerate process of data collection and accelerate research process
- Reduce participant burden with multiple short modules/questioner at regular intervals
- Gives all Army of Women members a chance to participate in research

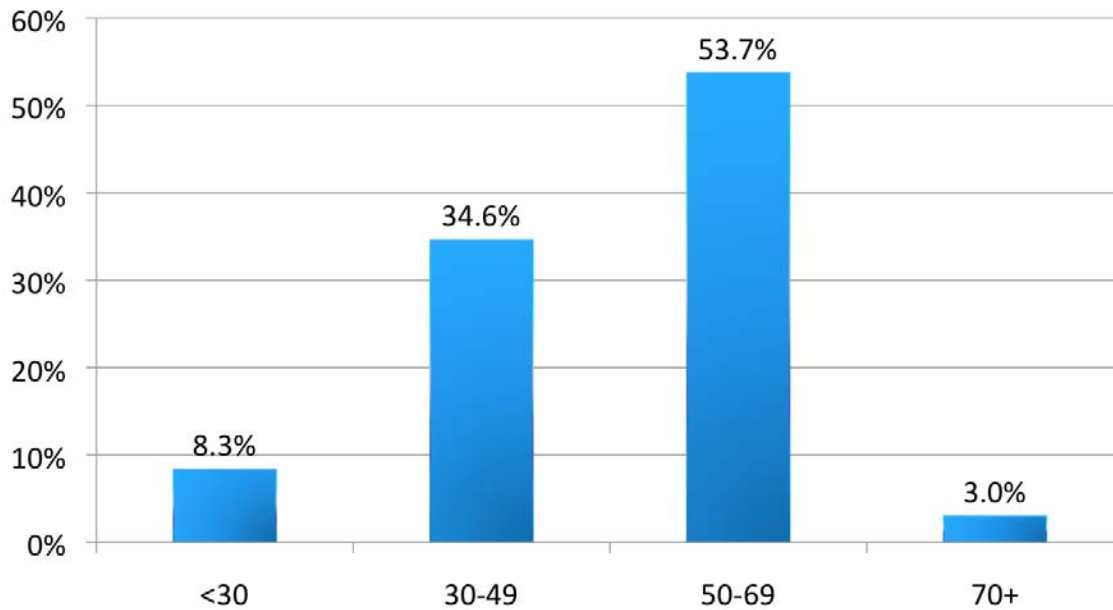
Approach

- Two cohorts
 - No prior diagnosis of breast cancer
 - Prior diagnosis of breast cancer
 - Modules diverge after collecting basic information to collect additional data from women with a past (baseline module) or new (subsequent modules) breast cancer

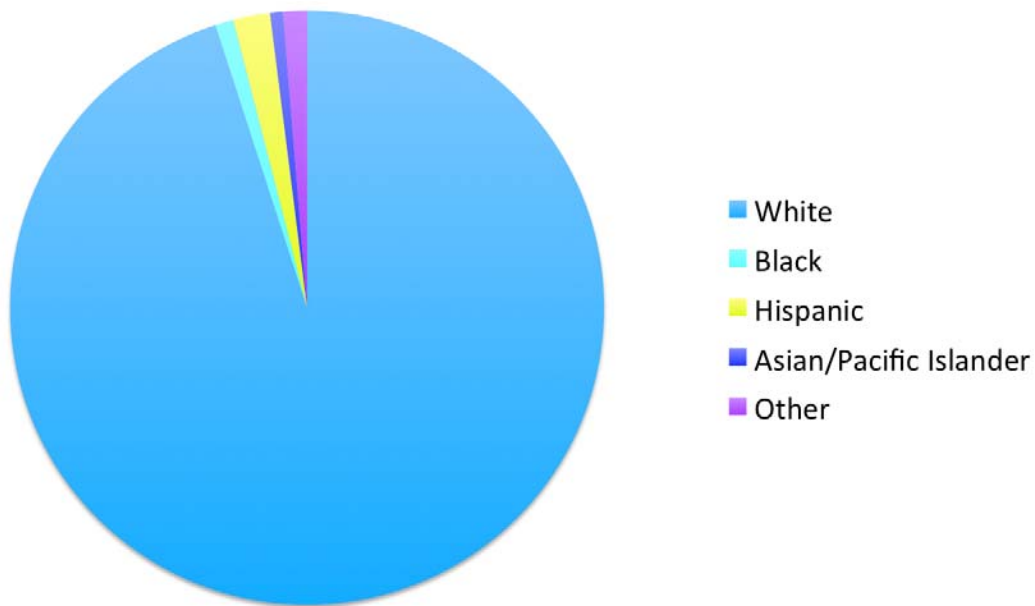
25,414 joined including 116 men



**Age distribution
(25,414 HOW beta Members)**



Race/Ethnicity HOW beta



Characteristics of HOW beta Members

- 18% are breast cancer patients
 - 4581 (18.1%) of females
 - 28 (24.1%) of males
- 97% self identify as white
- 90% had at least one term pregnancy
- 28% are overweight and 23% are obese

Diagnosis age and years since diagnosis: 4,471 women with breast cancer in the HOW Study, Wave 1

	Women with Breast Cancer	
	N	%
<u>Age at diagnosis</u>		
< 45	1340	30
45 – 54	1912	43
55 – 64	992	22
65+	185	4.
Unknown	42	1
<u>Years since diagnosis</u>		
< 1 yrs	49	1
1 – 4 yrs	1911	43
5 – 9 yrs	1196	27
10+ yrs	1273	29
Unknown	42	1

Stage at diagnosis: 4,471 women with breast cancer in the HOW Study, Wave 1

	Women with Breast Cancer	
	N	%
<u>Stage at diagnosis</u>		
In Situ (DCIS/LCIS)	1060	24
Stage I	1422	32
Stage II	1347	30
Stage III	410	9
Stage IV (metastatic disease)	59	1
Unknown/Missing	173	4

Comparison to an Existing Cohort

HOW beta Study

- Recruited through one email in December 2009
- Directed to register at a website and fill out an online module between 12/08/09 – 07/02/2010
- 25,414 (8%) respondents completed the module

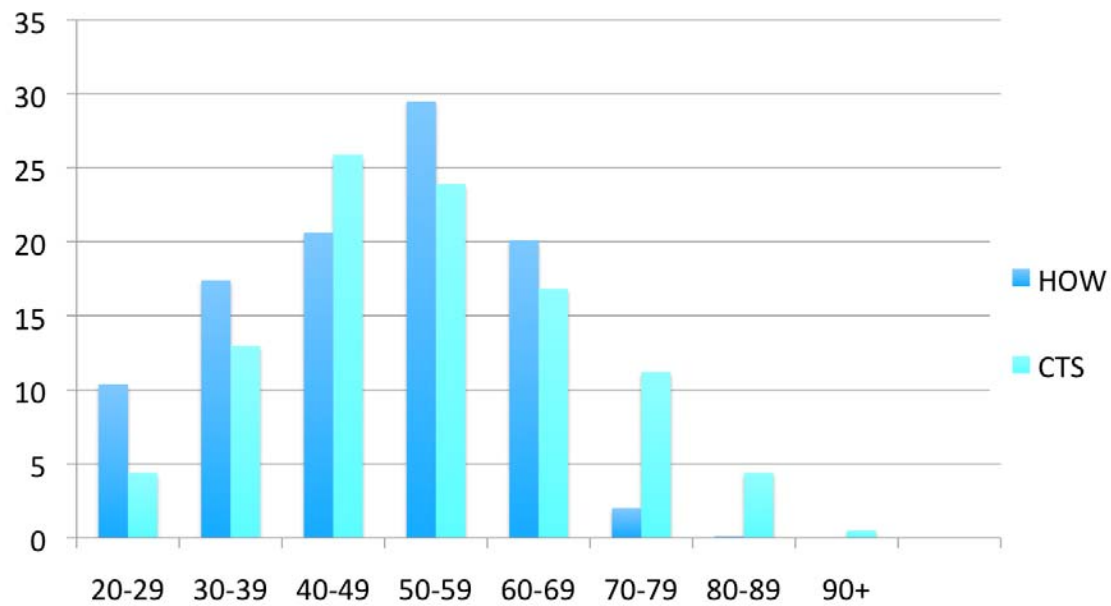
California Teacher's Study (CTS)

- Recruited through two mailings to 300,000 teachers in California between 1995-1996
- They were sent 16 page detailed questionnaire
- 133,476 (44%) returned the questionnaire

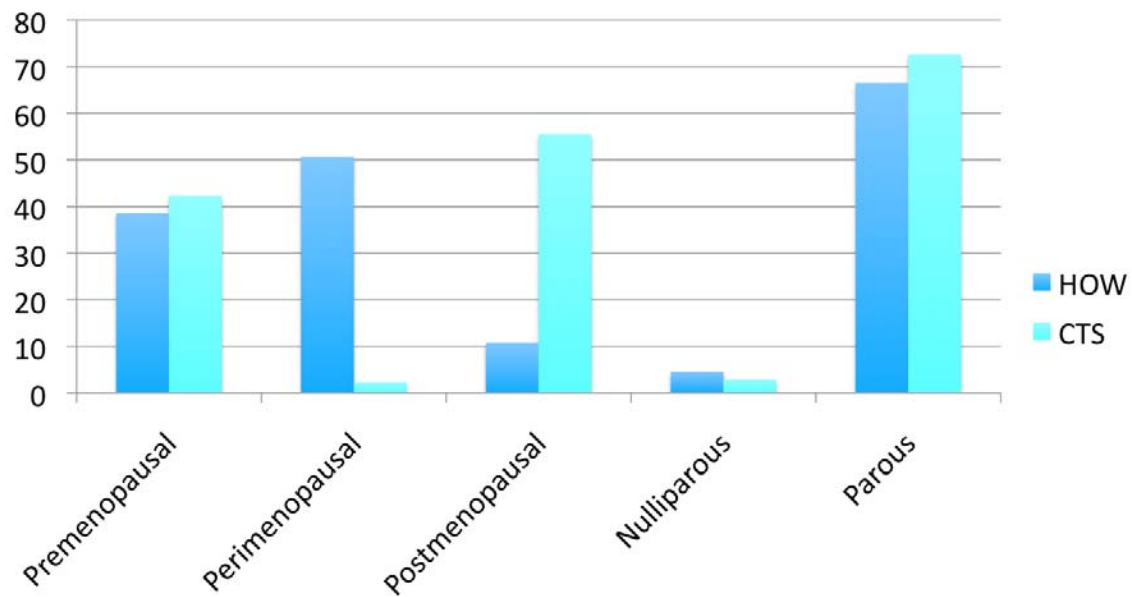
Comparison of HOW beta to CTS

	HOW beta		CTS	
N	20,715		126,549	
Race/Ethnicity				
White	19,645	94.8%	109,588	86.6%
Black	203	1.0%	3,384	2.7%
Hispanic	427	2.1%	5,251	4.2%
Asian/Pacific Islanders	151	0.7%	4,387	3.5%
Other/unknown	289	1.4%	3,939	3.1%

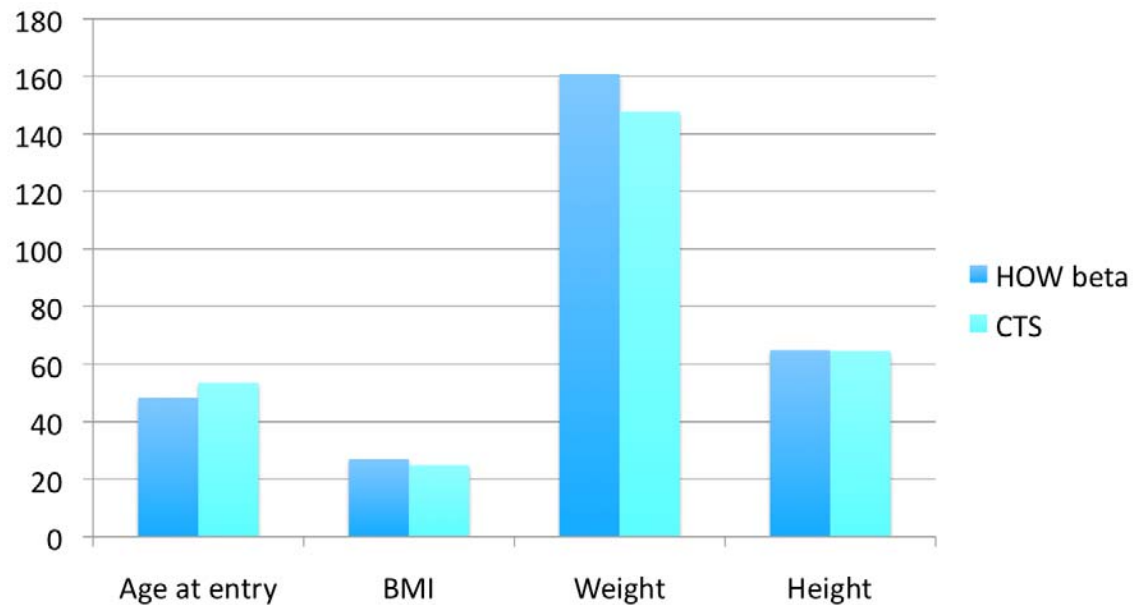
Age Comparison: HOW beta vs CTS



Reproductive History: HOW beta vs CTS



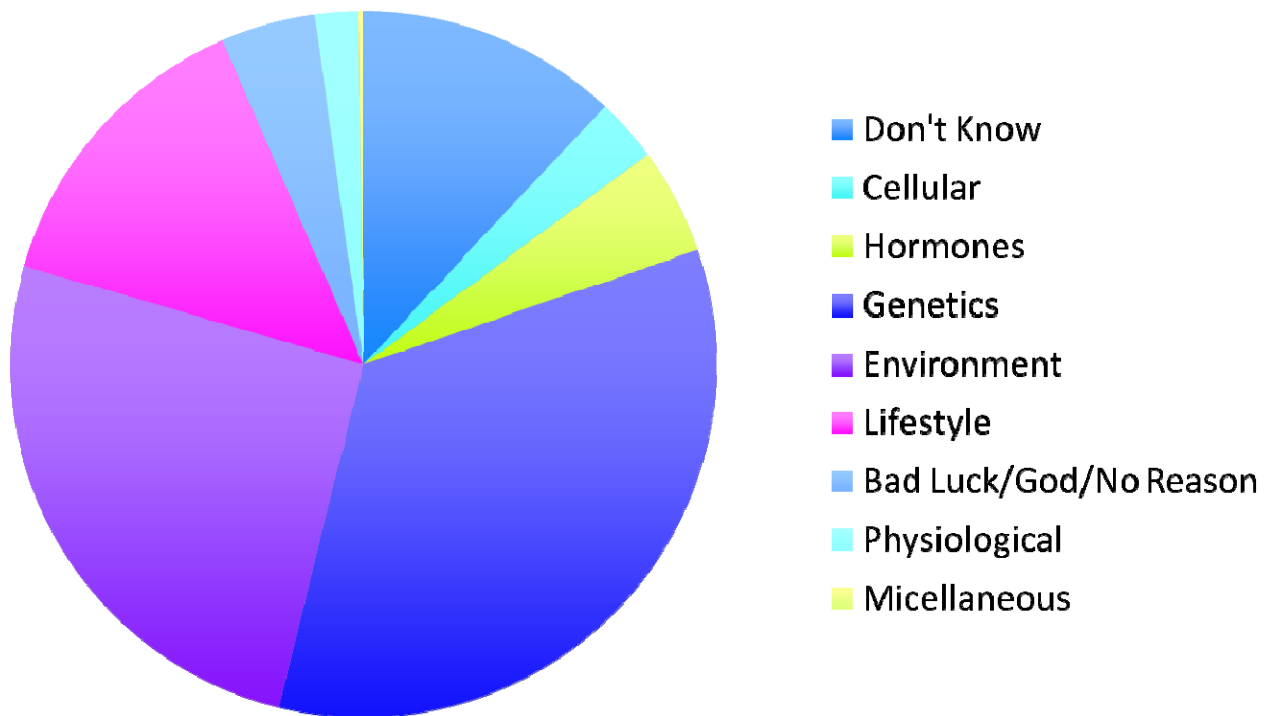
Comparison HOW beta to CTS



Involving Public in Asking the Questions

- Each module will solicit questions from the public
- Particular advocacy groups will help design questions relevant to their experience
 - Metastatic Disease
 - Transsexuals
 - Fertility Issues

What Causes Breast Cancer



Launch October

- Next steps:
 - Opt in for other diseases
 - Rent a Module
 - Working with women to develop modules
 - Mobile phone apps

Democratizing Research

The Love/Avon Army of Women needs YOU!

- Register yourself
- Encourage your family, and friends to register
- Submit your studies/questions

www.armyofwomen.org